K073162

510(k) Summary

Submitted by:	Kensey Nash Corporation 735 Pennsylvania Drive Exton, PA 19341
Prepared by:	Jennifer J. Bosley, Regulatory Affairs Manager
Contact Person:	Robin Fatzinger, VP Clinical & Regulatory Affairs Ph: (484) 713-2100 Fax: (484) 713-2903
Date Prepared:	November 7, 2007
Device Trade Name:	Safe-Cross® Radio Frequency Total Occlusion Crossing System
Common/Usual Name:	Wire, Guide, Catheter
Proposed Classification:	Catheter Guide Wire 21CFR § 870.1330 Class II, DQX—74 Cardiovascular

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Device Description:
The Safe-Cross® Radio Frequency Total Occlusion Crossing System provides Optical Coherence Reflectometry for navigation through vessels allowing visualization of the location of the Safe-Cross Crossing Wire tip. Radio Frequency energy is provided to the wire's distal tip in order to ablate tissue to create a passage for wire advancement through difficult sections of arterial occlusions. The System was modified to add a High Dynamic Range Console to the product line, which allows more light to penetrate and reflect off tissue improving the overall range of the system; and to modify the Crossing Wires to reinforce the distal tip.

The Safe-Cross Crossing Wires are provided EtO sterile for single use in the following sizes:

- .014" x 275 cm, straight or angled tip packaged with Safe Torquer and tip shaping tool; Coronary and Peripheral use.
- .035" x 275 cm, straight or angled tip packaged with Safe-Cross Torquer; Peripheral use only.

Intended Use:
The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in percutaneous interventions in native coronary and peripheral arteries with total occlusions. The device is not to be used in the carotid arteries.

Predicate Devices:
K050915 – Safe-Cross® Radio Frequency Total Occlusion Crossing System (Intraluminal Therapeutics)
K050916 – Safe-Cross® Radio Frequency Total Occlusion Crossing System (Intraluminal Therapeutics)

Substantial Equivalence:
The modified Safe-Cross System is substantially equivalent to the legally marketed predicate Safe-Cross devices now manufactured by Kensey Nash Corporation. Devices have same basic design and same materials, processing, intended use and fundamental scientific technology.

Non-Clinical Testing:
The Safe-Cross System has undergone the following testing: Console optics module verification and software validation; Crossing Wire biocompatibility, tensile, friction, torque response/strength and package integrity. Testing provides reasonable assurance of safety and effectiveness for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Kensey Nash Corporation
c/o Ms. Robin Fatzinger
Vice President, Clinical & Regulatory Affairs
735 Pennsylvania Drive
Exton, PA 19341

Re: K073162
Safe-Cross® Radio Frequency Total Occlusion Crossing System
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: January 10, 2008
Received: January 11, 2008

Dear Ms. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K073162

Device Name: **Safe-Cross® Radio Frequency Total Occlusion Crossing System**

Indications For Use:

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Prescription Use X	AND/OR	Over-The-Counter Use
(Per 21 CFR 801 Subpart D)		(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

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